

APPLICANT(S): KEREN, Gad et al.

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AMENDMENTS TO THE DRAWINGS

The attached sheet of drawings replaces the original sheet for Figure 3. The replacement figure corrects a typographic error in prior Figure 3. "Interior" has been changed to "Inferior". No new matter has been added.

Attachment: Replacement Sheet

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REMARKS

The present Amendment is intended to be fully responsive to all points of objection and/or rejection raised by the Examiner and is believed to place the application in condition for allowance. Favorable reconsideration and allowance of the application is respectfully requested.

Applicants assert that the present invention is new, non-obvious and useful. Prompt reconsideration and allowance of the claims are respectfully requested.

Status of Claims

Claims 32-58 are pending in the application.

Claims 1, 2, and 4-31 have been cancelled. Claims 32-58 have been added.

Remarks to the Drawings

The attached sheet of drawings replaces the original sheet for Figure 3. The replacement figure corrects a typographic error in prior Figure 3. "Interior" has been changed to "Inferior". No new matter has been added.

Remarks to Cancelled Claims and New Claims

Applicants have cancelled claims 1, 2, and 4-31 without prejudice. In making this cancellation without prejudice, Applicants reserve all the rights in these claims to file divisional and/or continuation patent applications.

Applicants have added new claims 32-58 to further define what Applicants consider to be their invention. It is respectfully submitted that the newly added claims meet all formal requirements, add no new matter to the application, and are fully supported by the original specification.

It is respectfully submitted that none of the cited references, in particular, none of Bailey et al. (US 6,458,153), Wilk (US 5,429,144), Lederman (US 6,210,318), and Korakianitis et al. (US 6,632,169), alone or in combination, teaches, suggests, or implies new independent claims 32, 41, 49 and 54 of the present application.

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For example, with regard to new independent claim 32, none of the cited references teaches, suggests, or implies, at least, the feature of an apparatus including a valve element “to selectively permit blood flow from said first atrium to a second atrium of said heart”, as recited in claim 32.

Bailey describes a valve prosthesis that may be used between the left atrium and the left ventricle to permit blood flow. Bailey fails to describe an apparatus that may be used between two atria to permit blood flow from a first atrium to a second atrium, as is required by claim 32. Bailey does not teach, suggest, or imply use of the prosthesis between two atria because Bailey’s prosthesis “is particularly well-adapted for mitral valve replacement” (column 1, line 22-25), and is “implanted in the position of the mitral valve and excluding the anatomic mitral valve MV” (column 11, lines 14-15).

Wilk describes a stent that may be disposed in the myocardium, either partially into the myocardium to permit blood flow from either the left ventricle or a coronary artery to veins of the heart, or completely through the heart wall to permit blood flow between the left ventricle and a coronary artery. Wilk fails to describe an apparatus that may be used between two atria to permit blood flow from a first atrium to a second atrium, as is required by claim 32. Wilk does not teach, suggest, or imply use of the stent between two atria because Wilk’s stent is used to “provide a method for performing a coronary artery by-pass operation” (column 1, lines 31-33).

Lederman describes a pumping balloon configured to be positioned within a desired body passageway to pump a fluid though the body passageway. Lederman fails to describe an apparatus that may be used between two atria to permit blood flow from a first atrium to a second atrium, as is required by claim 32. In fact, Lederman’s pumping balloon is used as “a cardiac support system located in ascending aorta 152 between aortic valve 154 and ostium of innominate artery 156” (column 5, lines 16-18).

Korakianitis describes a left ventricular assist device that is situated in place of the ascending aorta to pump blood into the aortic arch (column 26, lines 32-43). Korakianitis fails to describe an apparatus that may be used between two atria to permit blood flow from a first atrium to a second atrium, as is required by claim 32.

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For reasons similar to those discussed above with respect to new independent claim 32, Applicants respectfully submit that none of the above cited references teaches, suggests, or implies at least a method of "allowing blood to flow from the first atrium to a second atrium via a shunt", as recited in claim 41. Applicants further submit that none of the above cited references teaches, suggests, or implies at least a method of "implanting a shunt using a catheter between said first atrium and a second atrium", as recited in claim 49. Applicants further submit that none of the above cited references teaches, suggests, or implies at least "a blood flow diverting apparatus to be implanted inside the heart, on the atrial septum" as required by Applicants' new claim 54.

In view of the above arguments, Applicants respectfully submit that new independent claims 32, 41, 49 and 54 are not anticipated by any of the cited references. Furthermore, Applicants submit that claims 32, 41, 49 and 54 would not have been obvious to a person of ordinary skill in the art at the time the invention was made in light of the prior art of record, and therefore, are clearly patentable over all the cited prior art references, alone or in combination.

Each of dependent claims 33-40, 43-48, 50-53 and 55-58 depend from and therefore include at least all the features of one of claims 32, 41, 49 or 54. Therefore, Applicants respectfully submit that new claims 33-40, 43-48, 50-53 and 55-58 are patentable at least for the reasons discussed above regarding claims 32, 41, 49 and 54.

In view of the above, it is respectfully submitted that new claims 32-54 are in condition for allowance.

Objections to Drawings

The Examiner objected the drawings under 37 CFR 1.84(p)(5) for including reference character 135 that is not mentioned in the description.

Applicants have amended the specification, which now refers to reference character 135 in paragraph [0025]; and thus Applicants request that the Examiner's objection to the drawings under 37 CFR 1.84(p)(5) be withdrawn.

The Examiner objected the drawings under 37 CFR 1.83(a) for not showing every features of the invention specified in the claims 2, 8, 18, 23-26, 28 and 30.

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Applicants have voluntarily cancelled claims 2, 8, 18, 23-26, 28 and 30. Therefore, the Examiner's objections to these drawings are now moot.

Objections to Specification

The Examiner objected to the amendments submitted on September 28, 2004 for being incorrectly labeled.

Applicants respectfully submit that the instant amendments are correctly labeled, and cure the informalities as objected by the Examiner. Applicants further assert that the amendments are editorial in nature and no new matter has been added.

The Examiner objected to the amendments submitted on September 28, 2004 as allegedly adding new matter into the application. In particular, the Examiner alleges the subject matter of claims 24, 26, 28 and 30 constitute new matter.

Without commenting on the substance of the new matter rejection, Applicants have cancelled claims 24, 26, 28 and 30 without prejudice. Therefore, the Examiner's objections to claims 24, 26, 28 and 30 as adding new matter are now moot.

Claim Objections

In the Office Action, the Examiner objected to claims 26 and 27 as having insufficient antecedent basis for the use of term "the first portion".

Claims 26 and 17 have been cancelled without prejudice. Therefore, the Examiner's objections to claims 26 and 27 are now moot.

Claim Rejections - 35 U.S.C. § 112

In the Office Action, the Examiner rejected claims 24, 26, 28 and 30 under 35 USC 112, first paragraph, as allegedly failing to comply with written description requirement. In particular, the Examiner alleges that claims 24, 26, 28 and 30 contain new matter. In addition, the Examiner rejected claim 23 under 35 USC 112, second paragraph, as allegedly being indefinite. In particular, the Examiner alleges that claim 23 fails to point out and distinctly claim the subject matter that Applicants regard as the invention.

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Without commenting on the substance of the rejection, Claims 23-24, 26, 28 and 30 have been cancelled without prejudice. Therefore, the Examiner's rejections to claims 23-24, 26, 28 and 30 are now moot.

Applicants respectfully request that the Examiner's rejections to claims 23-24, 26, 28 and 30 under 35 USC 112 be withdrawn.

Claim Rejections - 35 U.S.C. § 102

In the Office Action, the Examiner rejected claims 1, 4, 9-14, 19-22, 25, 27, 29 and 31 under 35 USC 102(e) as being anticipated by Bailey et al. (US 6,458,153).

Claims 1, 4, 9-14, 19-22, 25, 27, 29 and 31 have been cancelled without prejudice. Applicants have added independent claims 32, 41, 49 and 54, and dependent claims 33-42, 44-50 and 52-54 that are novel, non-obvious, and patentable, as discussed above in the section entitled "Remarks to Cancelled Claims and New Claims".

Applicants respectfully request that the Examiner's rejections to claims 1, 4, 9-14, 19-22, 25, 27, 29 and 31 under 35 USC 102(e) as being anticipated by Bailey et al. be withdrawn.

In the Office Action, the Examiner rejected claims 1-2, 9-14, 19-22, 26, 28 and 30 under 35 USC 102(b) as being anticipated by Wilk (US 5,429,144).

Claims 1-2, 9-14, 19-22, 26, 28 and 30 have been cancelled without prejudice. Applicants have added independent claims 32, 41, 49 and 54, and dependent claims 33-42, 44-50 and 52-54 that are novel, non-obvious, and patentable, as discussed above in the section entitled "Remarks to Cancelled Claims and New Claims".

Applicants respectfully request that the Examiner's rejections to claims 1-2, 9-14, 19-22, 26, 28 and 30 under 35 USC 102(b) as being anticipated by Wilk be withdrawn.

Claim Rejections - 35 U.S.C. § 103

In the Office Action, the Examiner rejected claims 5, 7-8, 15 and 17-18 under 35 USC 103(a) as being unpatentable over Bailey et al. in view of Lederman (US 6,210,318).

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Claims 5, 7-8, 15 and 17-18 have been cancelled without prejudice. Applicants have added independent claims 32, 41, 49 and 54, and dependent claims 33-42, 44-50 and 52-54 that are novel, non-obvious, and patentable, as discussed above in the section entitled "Remarks to Cancelled Claims and New Claims".

Applicants respectfully request that the Examiner's rejections to claims 5, 7-8, 15 and 17-18 under 35 USC 103(a) as being unpatentable over Bailey in view of Lederman be withdrawn.

In the Office Action, the Examiner rejected claims 6 and 16 under 35 USC 103(a) as being unpatentable over Bailey et al. in view of Korakianitis et al. (US 6,632,169).

Claims 6 and 16 have been cancelled without prejudice. Applicants have added independent claims 32, 41, 49 and 54, and dependent claims 33-42, 44-50 and 52-54 that are novel, non-obvious, and patentable, as discussed above in the section entitled "Remarks to Cancelled Claims and New Claims".

Applicants respectfully request that the Examiner's rejections to claims 6 and 16 under 35 USC 103(a) as being unpatentable over Bailey in view of Korakianitis be withdrawn.

In the Office Action, the Examiner rejected claims 5, 7-8, 15 and 17-18 under 35 USC 103(a) as being unpatentable over Wilk in view of Lederman.

Claims 5, 7-8, 15 and 17-18 have been cancelled without prejudice. Applicants have added independent claims 32, 41, 49 and 54, and dependent claims 33-42, 44-50 and 52-54 that are novel, non-obvious, and patentable, as discussed above in the section entitled "Remarks to Cancelled Claims and New Claims".

Applicants respectfully request that the Examiner's rejections to claims 5, 7-8, 15 and 17-18 under 35 USC 103(a) as being unpatentable over Wilk in view of Lederman be withdrawn.

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In the Office Action, the Examiner rejected claims 6 and 16 under 35 USC 103(a) as being unpatentable over Wilk in view of Korakianitis et al.

Claims 6 and 16 have been cancelled without prejudice. Applicants have added independent claims 32, 41, 49 and 54, and dependent claims 33-42, 44-50 and 52-54 that are novel, non-obvious, and patentable, as discussed above in the section entitled "Remarks to Cancelled Claims and New Claims".

Applicants respectfully request that the Examiner's rejections to claims 6 and 16 under 35 USC 103(a) as being unpatentable over Wilk in view of Korakianitis be withdrawn.

Remarks to Response to Arguments

In the Office Action, the Examiner alleges that Applicants' arguments filed on September 28, 2004 are not persuasive. In particular, the Examiner contends that a coronary artery is a "chamber". In addition, the Examiner disagrees with Applicants' argument that Wilk does not disclose using pressure thresholds for selectively controlling blood flow.

Without conceding the correctness of the Examiner's response to Applicants' arguments submitted on September 28, 2004, Applicants have voluntarily cancelled claims 1-32. This cancellation of claims 1-32 makes the arguments submitted on September 28, 2004 and the Examiner's response to the arguments in this Office Action now moot.

Conclusion

Applicants believe that upon reviewing the above amendments and remarks, the Examiner will appreciate that the changes in the claims relate to subject matter already within the scope of the searches and discussions to date, and that entry of these amendments will not require additional searches and will not impose any additional burden on the Examiner.

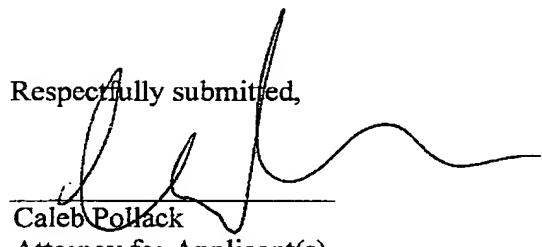
For at least the reasons discussed above, Applicants respectfully submit that all pending claims are now in condition for allowance. Their favorable reconsideration and allowance is respectfully requested.

Should the Examiner have any question or comment as to the form, content or entry of this Amendment, the Examiner is requested to contact the undersigned at the telephone

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number below. Similarly, if there are any further issues yet to be resolved to advance the prosecution of this application to issue, the Examiner is requested to telephone the undersigned counsel.

Applicants authorize the Office to charge the \$275.00 small entity fees for the 7 (seven) new claims over 20 and 1 (one) new independent claim over four to deposit account No. 05-0649. No additional fees are believed to be due in connection with this paper. If any such fees are due, please charge such fees to deposit account No. 05-0649.

Respectfully submitted,

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